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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/433,429	11/04/1999	SHAUN A. KIRKPATRICK	11160	2571

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EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT PAPER NUMBER

1636

DATE MAILED: 06/03/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/433,429

Applicant(s)

KIRKPATRICK, SHAUN A.

Examiner

Konstantina Katcheves

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 25-31 is/are pending in the application.
- 4a) Of the above claim(s) 1-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-20 and 25-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-20 and 25-31 are pending in the present application. Claims 18-20 and 25-31 are currently under examination.

Response to Amendment

The rejection of claims 19-26 are rejected under 35 U.S.C. 112, second paragraph has been withdrawn in view of Applicant's Amendment filed 8 January 2002.

The rejection of claims 18-20, 25, and 26 under 35 U.S.C. 102(b) as being anticipated by Gorman (EP 0 260 148 A2) has been withdrawn in view of Applicant's Amendment filed 8 January 2002.

The rejection of claims 18, 19, and 25 under 35 U.S.C. 102(b) as being anticipated by Jiang et al. (1997. Gene 185:285-290; see also the PubMed printout at the end of the document citing the month of publication as February.) has been withdrawn in view of Applicant's Amendment filed 8 January 2002.

The rejection of claims 18, 19, and 25 under 35 U.S.C. 102(b) as being anticipated by Blanchard et al. (1997. Biology of Reproduction 56:495-500, on Applicant's IDS) has been withdrawn in view of Applicant's Amendment filed 8 January 2002.

The rejection of claims 18-20, 25, and 26 under 35 U.S.C. 102(a) as being anticipated by Ducray et al. (May/June 1998. Steroids 63:285-287) has been withdrawn in view of Applicant's Amendment filed 8 January 2002.

Claims 18-20, 25 and 26 stand rejected and amended claims 18-26 and new claims 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gorman in view of Builder et al.

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(U.S. Patent 5,663,304), Meulien (U.S. Patent 5,521,070), Ritter et al. (1991. Journal of Biological Chemistry. 266:1043-1047) and Ciotti et al. (1996. Biochemistry 35:10119-10124) for the reasons of record set forth in the Office Action mailed 22 March 2001.

Response to Arguments

Claims 18-20, 25 and 26 stand rejected and amended claims 18-26 and new claims 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gorman in view of Builder et al. (U.S. Patent 5,663,304), Meulien (U.S. Patent 5,521,070), Ritter et al. (1991. Journal of Biological Chemistry. 266:1043-1047) and Ciotti et al. (1996. Biochemistry 35:10119-10124) for the reasons of record set forth in the Office Action mailed 22 March 2001. Applicant's arguments filed 8 January 2002 have been fully considered but they are not persuasive.

Applicant argues first that none of the references, including Gorman et al., teach a Sertoli cell comprising the vector which creates an immunologically privileged response *in vivo*. Applicant should note that the above-cited references together teach the claimed invention. They are not cited for the teachings individually. Moreover, so long as the references teach the elements of the claimed invention such that it would have been obvious to one of skill in the art, the mechanism by which the vector and transformed cells work is not relevant nor does it render the claims patentably distinct over the prior art.

Applicant cites *In re Vaeck*, 947 F2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991) that there is no suggestion is implicit or explicit in the prior art to carry out the claimed invention. Contrary to Applicant's assertion motivation to combine the instant references does indeed exist. Gorman teaches in the working examples, effective production of biological factors

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in Sertoli cells which suggests that the production of various biological factors in Sertoli cells. The suggestion of Gorman taken in light of Builder which specifically discloses Factor IX as a polypeptide of interest and Sertoli cells as useful mammalian cells, the ordinary skilled artisan would have been motivated to produce biological factors of interest in Sertoli cells. One would have also been motivated to use a promoter that functioned in the cells, as well as 3' termination signals, so that the polypeptides would be expressed. Since many biological factors, such as Factor VIII, Factor IX, and B-UGT, have signal sequences, which are upstream of the coding region of the rest of the protein and downstream of any promoter, there would have been motivation to include those signal sequences (encoding signal peptides) in vectors for expressing the biological factors.

Applicant also asserts that Muelin et al., Ritter et al. and Ciotti et al. do not even teach Sertoli cells. Applicant has apparently misinterpreted the reason for which these references were cited. Gorman et al. and Builder et al. teach Sertoli cells. These references are cited for what they teach together not individually.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves
June 3, 2002


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